Department of Veterans Affairs **VHA DIRECTIVE 2003-036**
Veterans Health Administration
Washington, DC 20420 **July 7, 2003**

CREDENTIALS AND TRAINING OF EMPLOYEES INVOLVED IN HUMAN SUBJECTS RESEARCH

1. PURPOSE: This Veterans Health Administration (VHA) Directive defines the policy for credentialing or otherwise validating the qualifications of employees involved in human subjects research.

2. BACKGROUND

a. The Department of Veterans Affairs (VA) is guided by the ethical principles set forth in the Common Rule, Food and Drug Administration (FDA) regulations, and the Belmont Report. With the increased complexity of research and the advent of new technologies it is imperative that all VHA personnel involved in human subjects research have and maintain the appropriate expertise through education, training, and experience. Such a level of education and expertise is essential in a human research protection program that strives to provide the highest level of protection to its human subjects.

b. The following definitions apply throughout this Directive:

(1) **Background Investigation.** The level of background investigation needs to reflect the risk level assigned to the employee's position (see VA Handbook 0710 for further information associated with the risk level assigned to the employee's position).

(2) **Belmont Report.** This term refers to the "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" developed by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research on April 18, 1979.

(3) **Common Rule.** This term refers to a common set of regulations governing human subjects research published in the Federal Register (56 FR 28003) as the final Federal policy for the Protection of Human Subjects. The VA regulations under this "Common Rule" are codified at Title 38 Code of Federal Regulations (CFR) Part 16. ***NOTE:*** *The "Common Rule" was developed to ensure protection of the rights and welfare of individuals involved as subjects of research.*

(4) **Credentialing.** Credentialing is the formal, systematic process of verifying, screening, and evaluating qualifications and other credentials that include education, licensure, relevant training and experience, and current competence. ***NOTE:*** *VHA policy related to credentialing may be found in VHA Handbook 1100.19; it also refers to the requirements for screening credentials of Title 38 employees who are not licensed independent practitioners (see VA Handbook 5005, Part II, Chapter 3, Section B).*

(5) **Institutional Review Board (IRB).** An IRB is established in accordance with and for the purposes expressed in the Common Rule. It is a committee established to protect the

rights and welfare of human research subjects and is comprised of scientists and non-scientists. ***NOTE:*** *Within VHA, an IRB is also known as the Subcommittee on Human Studies. Additional information may be found in VHA Manual M-3, Part I, Chapters 2, 3, and 9.*

(6) **Licensed Independent Practitioner (LIP).** LIP refers to any individual permitted by law and the facility to provide patient care services independently; i.e., without supervision or direction, within the scope of the individual's license and in accordance with individually granted clinical privileges. Only independent LIPs may be granted clinical privileges, and they must be credentialed through VetPro, VHA's national electronic credentials databank. ***NOTE:*** *Only practitioners who are licensed and permitted by law and the facility to practice independently may be granted clinical privileges.*

(7) **Research and Development Committee (R&D).** The R&D committee is a local committee charged with oversight of all R&D activities within a facility. The IRB, when established by the VA facility, is a subcommittee of the R&D committee. If the services of an affiliated university IRB are obtained, the R&D committee has an oversight responsibility for the research being conducted at the VHA facility and verifies that the IRB is in compliance with all applicable regulations and policies.

(8) **Scope of Practice Statement.** A scope of practice statement outlines the duties of employees involved in human studies research that are authorized by the Principal Investigator. A scope of practice statement outlines the duties a research employee, other than an LIP (LIPs are granted clinical privileges in lieu of a scope of practice), is authorized to perform during the conduct of a research study. A scope of practice statement needs to be developed for each employee, not each protocol. Research staff involved in multiple studies need to have one scope of practice that encompasses all of the routine duties that they are authorized to perform. ***NOTE:*** *The Scope of Practice is granted and signed by the Principal Investigator(s) and reviewed and approved by the Associate Chief of Staff (ACOS) for Research.*

(9) **Validation of Credentials.** The validation of credentials refers to the verification of the degree and license of employees, appointed under Title 5 United States Code (U.S.C.), to positions that have positive education and/or licensure or registration requirements. All credentials are to be validated through primary sources, whenever feasible.

3. POLICY: It is VHA policy that all employees involved in human subjects research, regardless of appointment mechanism (Title 38, Title 5, or Without Compensation (WOC)), must possess adequate credentials and training to ensure their understanding of the protection of human subjects and the ethical conduct of research. **Authority:** *Title 38 U.S.C. Section 7304.*

4. ACTION

a. **Chief R&D Officer (CRADO).** The CRADO must work with the Deputy Under Secretary for Health for Operations and Management and VISN Directors to ensure the provisions of this Directive are implemented.

b. **VISN Directors.** Each VISN Director is responsible for establishing controls to monitor continuing compliance with the provisions of this Directive.

c. **Medical Center Directors.** Facility Directors with human subject research programs must:

(1) Ensure establishment of an IRB Committee and an R&D Committee that functions as required by VHA Manual M-3, Part I, Chapters 2, 3, and 9; VHA Directive 1200, and the Common Rule.

(2) Ensure individuals involved in human subjects research receive appropriate training in the ethical principles and good clinical practices for human subjects research on an annual basis. The training requirement applies to all individuals, other than secretarial support, involved in human subjects research (e.g., Chief of Staff (COS), ACOS for Research, investigators, research coordinators and assistants, members of the R&D Committee, and members and staff of the IRB). All investigators, research coordinators, and research assistants involved in human subjects research, and all members of the Research Office, all members of the R&D Committee, and all members and staff of a VA IRB, exclusive of administrative support, will complete an educational course or complete a web-based course on both the protection of human research subjects, and Good Clinical Practice (GCP) as encompassed by the Food and Drug Administration (FDA) regulations. Investigators who can document completion of these courses in the past year will not be required to re-take the training at this time. All individuals subject to this policy will be required to update their training annually thereafter. VA investigators should use the National Cancer Institute's web-based course on Human Participant Protections Education for Research teams. ***NOTE:*** *The Office of Research and Development (ORD) has developed computer-based training in GCP, and CD-ROMs will be provided to any site that does not have Internet access. If the University affiliate provides the VA IRB function, the affiliate will be encouraged to participate in these educational activities.*

(3) Ensure all employees involved in human subjects research have had appropriate background investigations, have been credentialed or had their qualifications validated, and that licenses of individuals in positions requiring a license are verified for currency.

(4) Recommend or take disciplinary action against employees who fail to comply with the provisions of this Directive.

d. **Principal Investigators.** Principal investigators involved in human subjects research are responsible for ensuring that:

(1) All human subjects research has been approved by the IRB and the R&D Committee.

(2) All employees under their supervision involved in human subjects research have approved scope of practice statements or clinical privileges that are consistent with the employees' qualifications.

e. **Human Resources Officers and Credentialing Coordinators.** Human Resources Officers and Credentialing Coordinators are responsible for providing management officials with appropriate advice and assistance concerning:

(1) Requirements related to credentialing and validation of the qualifications of employees involved in human subjects research.

(2) Initiation of appropriate background investigations.

(3) Clinical privileging of LIPs.

(4) Other required employment screenings (Department of Health and Human Services (HHS), Exclusionary List, National Practitioner Data Bank, Federation of State Medical Boards, and FDA Debarment List).

(5) On-going verification of employee licenses and other qualifications.

f. **Employees Involved in Human Subjects Research**. Employees involved in human subjects research are responsible for:

(1) Knowing and adhering to the scope of practice or clinical privileges that have been approved for them.

(2) Knowing and adhering to applicable statutes, regulations, and policies related to conducting human subjects research.

(3) Completing required training in the ethical principles and acceptable human subjects research practices on an annual basis.

(4) Engaging only in human subjects research activities that have been approved, as required by VA regulations and policies.

5. REFERENCES

a. Title 21 Code of Federal Regulations (CFR) Parts 50,56, 312, and 812.

b. Title 38 U.S.C. Section 7304.

c. Title 38, CFR Part 16.

d. VA Handbook 5005, Staffing, Part II, Chapter 3, Section B.

e. VA Handbook 0710.

f. VHA Handbook 1100.19.

g. VHA Manual M-3, Part I, Chapters 2, 3, and 9.

h. VHA Directive 1200.

6. FOLLOW-UP RESPONSIBILITY: The Office of Research and Development (12) is responsible for the content of this Directive. Questions may be referred to (202) 254-0199.

7. RESCISSIONS: None. This VHA Directive expires July 31, 2008.

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Under Secretary for Health

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